

October 27, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.75

Subject: Reissuance of Product Licenses for Products Under Conditional Licenses

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum provides guidelines for reissuance of product licenses for products under conditional United States Veterinary Biological Product Licenses upon approach of the termination date of the conditional license according to 9 CFR 102.6(a).

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.75 dated June 2, 1985.

III. BACKGROUND

In order to meet an emergency condition, limited market, local situation, or other special circumstance, APHIS may issue a conditional United States Veterinary Biological Product License for a veterinary biological product under expedited procedures that ensure purity, safety, and a reasonable expectation of efficacy. APHIS may require establishments issued a conditional product license to do additional efficacy studies on the product or to develop additional data to support the validity of a proposed potency test for the product or both.

Each conditional product license carries a termination date. During the period the conditional license is in effect, the Center for Veterinary Biologics (CVB) expects the licensee either to make satisfactory progress toward completing the requirements for a regular product license or to fully complete the requirements for a regular product license.

IV. GUIDELINES

At the approach of the termination date of a conditional product license, CVB may either reissue the product license as a conditional product license or as a regular product license or allow the product license to terminate. This depends on the degree to which the licensee has demonstrated progress toward completing the requirements for a regular license.

A. Requests for Reissuance of a Product License

Before the date the conditional product license is to terminate, CVB must receive from the licensee a request for reissuance of the product license. The request should include all available data and information demonstrating progress the licensee has made toward completing the requirements for a regular license for the product.

B. CVB Actions

CVB will respond to a request to reissue the product license for a product under a conditional license by doing one of the following:

1. *Reissue the Product License as a Regular Product License* - If the licensee satisfies all the requirements for a regular product license, CVB will issue a regular product license for the product.
2. *Reissue the Product License as a Conditional Product License* - If the licensee makes satisfactory progress toward completing the requirements for a regular product license, but does not complete all the requirements for a regular product license, CVB will issue a conditional product license for the product.
3. *Allow the Product License to Terminate* - If the licensee does not demonstrate satisfactory progress toward completing the requirements for a regular product license, CVB will allow the product license to terminate.

C. Products That Have Been Qualified For Regular License by Other Licensees

CVB may consider the reissuance of a conditional product license, for a period not to exceed 6 months, if the product has been qualified for a regular product license by another manufacturer since the conditional product license was last issued. CVB may reissue such product licenses only if assured that the licensee can satisfy all requirements for issuance of a regular product license within that 6-month period. If such assurance cannot be provided, CVB may allow the product license to terminate.

/s/ Thomas E. Walton for

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